



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : <b>A61F 2/02</b>	<b>A1</b>	(11) International Publication Number: <b>WO 98/14136</b> (43) International Publication Date: 9 April 1998 (09.04.98)
--	-----------	---

(21) International Application Number: PCT/US97/17898

(22) International Filing Date: 1 October 1997 (01.10.97)

(30) Priority Data:  
08/720,556 2 October 1996 (02.10.96) US(71) Applicant: ACORN MEDICAL, INC. [US/US]; Suite 421,  
9900 Bren Road East, Minnetonka, MN 55343 (US).(72) Inventor: ALFERNESS, Clifton, A.; 2022 - 235th Place N.E.,  
Redmond, WA 98053 (US).(74) Agent: BRUESS, Steven, C.; Merchant, Gould, Smith, Edell,  
Welter & Schmidt, P.A., 3100 Norwest Center, 90 South  
Seventh Street, Minneapolis, MN 55402-4131 (US).

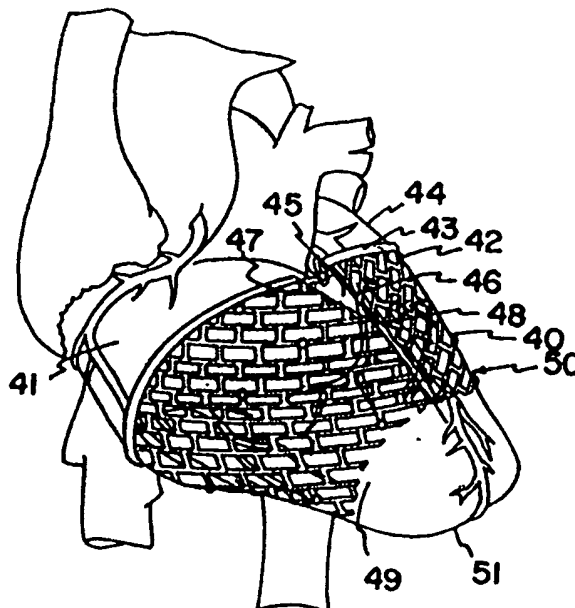
(81) Designated States: AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), EE, EE (Utility model), ES, FI, FI (Utility model), GB, GE, GH, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

**Published***With international search report.**Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.*

(54) Title: HEART VOLUME LIMITING DEVICE

## (57) Abstract

The present disclosure is directed to a cardiac reinforcement device (CRD) and method for the treatment of cardiomyopathy. The CRD provides for reinforcement of the walls of the heart by constraining cardiac expansion, beyond a predetermined limit, during diastolic expansion of the heart. A CRD of the invention can be applied to the epicardium of the heart to locally constrain expansion of the cardiac wall or to circumferentially constrain the cardiac wall during cardiac expansion.



**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

## HEART VOLUME LIMITING DEVICE

**Background of the Invention**

The present invention is generally directed to a device and method for  
5 reinforcement of the cardiac wall. The invention is particularly suited for the  
treatment of cardiac disease which result in atrial or ventricular dilation. The  
invention provides reinforcement of the cardiac wall during diastolic chamber filling  
to prevent or reduce cardiac dilation in patients known to have experienced such  
dilation or who have a predisposition for such dilation occurring in the future. The  
10 cardiac reinforcement structure is typically applied to the epicardial surface of the  
heart.

Cardiac dilation occurs with different forms of cardiac disease,  
including heart failure. In some cases, such as post-myocardial infarction, the  
dilation may be localized to only a portion of the heart. In other cases, such as  
15 hypertrophic cardiomyopathy, there is typically increased resistance to filling of the  
left ventricle with concomitant dilation of the left atria. In dilated cardiomyopathy,  
the dilation is typically of the left ventricle with resultant failure of the heart as a  
pump. In advanced cases, dilated cardiomyopathy involves the majority of the heart.

With each type of cardiac dilation, there are associated problems  
20 ranging from arrhythmias which arise due to the stretch of myocardial cells, to  
leakage of the cardiac valves due to enlargement of the valvular annulus. Devices to  
prevent or reduce dilation and thereby reduce the consequences of dilation have not  
been described. Patches made from low porosity materials, for example Dacron™,  
have been used to repair cardiac ruptures and septal defects, but the use of patches to  
25 support the cardiac wall where no penetrating lesion is present has not been  
described.

Drugs are sometimes employed to assist in treating problems  
associated with cardiac dilation. For example, digoxin increases the contractility of  
the cardiac muscle and thereby causes enhanced emptying of the dilated cardiac  
30 chambers. On the other hand, some drugs, for example, beta-blocking drugs,  
decrease the contractility of the heart and thus increase the likelihood of dilation.  
Other drugs including angiotensin-converting enzyme inhibitors such as enalapril  
help to reduce the tendency of the heart to dilate under the increased diastolic  
pressure experienced when the contractility of the heart muscle decreases. Many of  
35 these drugs, however, have side effects which make them undesirable for long-term  
use.

Accordingly, there is a need for a device that can reduce or prevent  
cardiac dilation and reduce the problems associated with such dilation.

### **Summary of the Invention**

The present invention is directed to a device and method for reinforcement of the cardiac wall. According to the invention, a cardiac reinforcement device includes a biomedical material which can be applied to the epicardial surface of the heart and which expands to a predetermined size that is selected to constrain cardiac expansion beyond a predetermined limit. A biomedical material suitable for a cardiac reinforcement device can be an elastic or non-elastic mesh or non-mesh material.

In one embodiment, a cardiac reinforcement device is a biomedical material in the form of a patch. The size of the patch is selected to locally constrain cardiac expansion.

In another embodiment, a cardiac reinforcement device is a biomedical material shaped as a jacket with a predetermined size selected for the jacket to surround the epicardial surface of the heart and circumferentially constrain cardiac expansion. In one embodiment, a cardiac reinforcement jacket may be applied to the epicardial surface via a minimally invasive procedure such as thoracoscopy.

A cardiac reinforcement jacket can include a securing arrangement for securing the jacket to the epicardial surface of the heart. The cardiac reinforcement jacket can also include a mechanism for selectively adjusting the predetermined size of the jacket around the epicardial surface of the heart. The adjustment mechanism can include a slot having opposing lateral edges which when pulled together decrease the volumetric size of the jacket. In an alternative embodiment, a selective size adjustment mechanism can include an inflatable member mounted between the jacket and the epicardial surface of the heart. Inflation of the inflatable member provides for reduction in the volumetric size of the jacket.

A cardiac reinforcement device of the invention can be used to treat cardiomyopathy or to reduce the diastolic volume of the heart.

### **Brief Description of the Drawings**

FIG. 1 is a frontal view of one embodiment of a cardiac reinforcement patch.

FIG. 2 is a perspective view of the cardiac reinforcement patch of FIG. 1 in place on the epicardium of a heart.

FIG. 3 is a perspective view of one embodiment of a cardiac reinforcement jacket according to the invention.

FIG. 4 is a second embodiment of a cardiac reinforcement jacket according to the invention.

FIG. 5 is a perspective view of the embodiment of the cardiac reinforcement jacket shown in FIG. 3 in place around the heart.

5           FIG. 6 is a schematic cross sectional view of one embodiment of a mechanism for selectively adjusting the predetermined size of a cardiac reinforcement jacket.

FIG. 7 is a perspective view of a placement tool which can be used for applying a cardiac reinforcement jacket.

10           FIG. 8 is a perspective view of a placement tool being employed to place a cardiac reinforcement jacket over the heart.

### **Detailed Description**

15           The present invention is directed to reinforcement of the heart wall during diastolic filling of a chamber of the heart. The invention is particularly suited for use in cardiomyopathies where abnormal dilation of one or more chambers of the heart is a component of the disease.

20           As used herein, "cardiac chamber" refers to the left or right atrium or the left or right ventricle. The term "myocardium" refers to the cardiac muscle comprising the contractile walls of the heart. The term "endocardial surface" refers to the inner walls of the heart. The term "epicardial surface" refers to the outer walls of the heart.

25           The heart is enclosed within a double walled sac known as the pericardium. The inner layer of the pericardial sac is the visceral pericardium or epicardium. The outer layer of the pericardial sac is the parietal pericardium.

30           According to the present invention, a cardiac reinforcement device (CRD) limits the outward expansion of the heart wall during diastolic chamber filling beyond a predetermined size. The expansion constraint applied to the heart by a CRD is predetermined by the physician based on, for example, cardiac output performance or cardiac volume. In contrast to known ventricular assist devices which provide cardiac assistance during systole, a CRD according to the present disclosure provides cardiac reinforcement during diastole.

35           A CRD is made from a biomedical material which can be applied to the epicardial surface of the heart. As used herein, a "biomedical material" is a material which is physiologically inert to avoid rejection or other negative inflammatory response. A CRD can be prepared from an elastic or substantially non-elastic biomedical material. The biomedical material can be inflexible, but is preferably sufficiently flexible to move with the expansion and contraction of the

heart without impairing systolic function. The biomedical material should, however, constrain cardiac expansion, during diastolic filling of the heart, to a predetermined size. Examples of suitable biomedical materials include perforate and non-perforate materials. Perforate materials include, for example, a mesh such as a polypropylene or polyester mesh. Non-perforate materials include, for example, silicone rubber.

A biomedical material suitable for a device of the invention generally has a lower compliance than the heart wall. Even though the biomedical material is less compliant than the heart wall, some limited expansion of an elastic biomedical material can occur during cardiac filling.

In an alternative embodiment, the biomedical material can be substantially non-elastic. According to this embodiment, the term "substantially non-elastic" refers to a material which constrains cardiac expansion during diastole at a predetermined size, but which has substantially no elastic properties.

Regardless if the biomedical material is elastic or non-elastic, advantageous to a CRD according to the present disclosure is cardiac reinforcement which is provided during diastole. Moreover, a CRD as disclosed herein does not provide cardiac assistance through active pumping of the heart.

#### **I. CRD Patch**

In one embodiment, a cardiac reinforcement device (CRD) provides for local constraint of the heart wall during cardiac expansion. According to this embodiment, a CRD is a "patch" that provides reinforcement of the heart wall at a localized area, such as a cardiac aneurysm or at an area of the myocardium which has been damaged due to myocardial infarction. When discussing a "patch", "predetermined size" of the patch means that the size of the patch is selected to cover an area of the epicardial surface of the heart in need of reinforcement without completely surrounding the circumference of the heart.

A CRD patch can be prepared from the biomedical materials described above. In a preferred embodiment, the patch is an open mesh material.

A CRD patch can be applied to the epicardial surface of the heart over or under the parietal pericardium. A patch is typically applied to the epicardial surface by suturing around the periphery of the patch. The peripheral edge of the patch can include a thickened "ring" or other reinforcement to enhance the strength of the patch at the point of suture attachment to the epicardium. Generally, a patch is applied to the epicardium through a thoracotomy or other incision providing sufficient exposure of the heart.

## II. CRD Jacket

In another embodiment, a CRD is a jacket that circumferentially surrounds the epicardial surface of the heart. When applied to the heart, a CRD jacket can be placed over or under the parietal pericardium.

5 A CRD applied to the epicardium is fitted to a "predetermined size" for limitation of cardiac expansion. According to a jacket embodiment, "predetermined size" refers to the predetermined expansion limit of the jacket which circumferentially constrains cardiac expansion during diastolic filling of the heart. In practice, for example, a physician could measure cardiac output and adjust the  
10 jacket size to an optimal size for the desired effect. In this example, the optimal size is the "predetermined size". In one embodiment, the predetermined size can be adjusted for size reduction as the cardiac size is reduced.

In one embodiment, the CRD jacket is a cone-shaped tube, having a base broader than the apex, which generally conforms to the external geometry of  
15 the heart. When applied to the epicardial surface of the heart, the base of the jacket is oriented towards the base of the heart, and the apex of the jacket is oriented towards the apex of the heart. Typically, the base of the jacket includes an opening for applying the jacket by passing the jacket over the epicardial surface of the heart. The apical end of the jacket can be a continuous surface which covers the apex of the  
20 heart. Alternatively, the apex of the jacket can have an opening through which the apex of the heart protrudes.

A cardiac reinforcement jacket, as disclosed herein, is not an inflatable device that surrounds the heart. Rather, the device is typically a single layer of biomedical material. In one embodiment discussed below, an inflatable  
25 member can be included with the device, but the inflatable member serves to reduce the volume within a localized region of the jacket and does not follow the entire jacket to surround the epicardial surface of the heart.

In one embodiment, the CRD jacket can be secured to the epicardium by a securing arrangement mounted at the base of the jacket. A suitable securing  
30 arrangement includes, for example, a circumferential attachment device, such as a cord, suture, band, adhesive or shape memory element which passes around the circumference of the base of the jacket. The ends of the attachment device can be fastened together to secure the jacket in place. Alternatively, the base of the jacket can be reinforced for suturing the base of the jacket to the epicardium.

35 Various sized CRD jackets can be prepared such that different sized jackets are used for different predetermined cardiac expansion sizes or expansion ranges. Alternatively, a CRD jacket can include a mechanism for selectively adjusting the size of the jacket. A mechanism for selectively adjusting the

volumetric size of the jacket theoretically provides for a "one size fits all" device. More importantly, however, an adjustable jacket provides the ability to titrate (readjust) the amount of cardiac reinforcement by graded reduction in jacket size as therapeutic reduction of cardiac expansion occurs.

5                   A mechanism for selectively adjusting the size of the jacket can include a slot which opens at the base of the jacket and extends toward the apex end of the CRD. If the apex end of the CRD jacket is open, the apical extent of the slot can be continuous with the apex opening. The slot includes opposing lateral edges. By adjusting the proximity of the opposing lateral edges, the overall size of the  
10 jacket can be varied. Moving the opposing edges of the slot closer together narrows the slot and reduces the volumetric size of the jacket. The opposing edges of the slot can be fastened together at a predetermined proximity by, for example, one or more lateral attachment devices, such as a cord, suture, band, adhesive or shape memory element attached to each lateral edge.

15                   In another embodiment, a mechanism for selectively adjusting the size of the jacket can be an inflatable member. According to this embodiment, the inflatable member is mounted between the jacket and the epicardium. The volumetric size of the jacket can be reduced by inflating the inflatable member through an inflation port with, for example, a gas or liquid. As cardiac expansion  
20 volume responds to cardiac constraint by size reduction, the predetermined size of the jacket can then be reduced by inflating the inflatable member within the jacket. Once inflated, the size of the inflatable member is preferably maintained until therapeutic response causes a need for further inflation. According to the invention, the inflation of the inflatable member provides a reduction in the predetermined size  
25 of the jacket by a fixed increase in volume of the inflatable member. The inflatable member is not rhythmically inflated and deflated to provide assistance to cardiac contraction during systole.

                  The biomedical material of the invention can be radioluscent or radiopaque. In one embodiment, the material of the jacket can be made radiopaque  
30 by inclusion of radiopaque markers for identification of the outside surface of the heart, the expansion slot or inflation port. As used herein, radiopaque means causing the CRD to be visible on x-ray or fluoroscopic viewing. Suitable radiopaque markers include, for example, platinum wires, titanium wires and stainless steel wires.

35                   A CRD according to the present disclosure provides a new method for the treatment of cardiac disease. As used herein, cardiac disease includes diseases in which dilation of one of the chambers of the heart is a component of the disease. Examples include heart failure or cardiomyopathy. Heart failure can occur



as a result of cardiac dilation due to ventricular hypertrophy or secondary to, for example, valvular incompetency, valvular insufficiency or valvular stenosis. Cardiomyopathy, according to the invention, can be primary or secondary to infection, ischemia, metabolic disease, genetic disorders, etc.

5           It is foreseen that constraint of cardiac expansion by a device of the invention can provide reduced cardiac dilation. Reduced cardiac dilation can cause reduction in the problems associated with cardiac dilation such as arrhythmias and valvular leakage. As reduction of cardiac dilation occurs, selective reduction of the predetermined size of the jacket also provides continued reinforcement for the size  
10 reduced heart.

          A CRD jacket can also be used to measure cardiac performance. According to this embodiment, the CRD jacket is rendered radiopaque by use of a radiographic marker. The radiographic markers are distributed throughout the jacket over the surface of the heart. By evaluation of the markers relative to one another  
15 with each heart beat, cardiac performance may be measured. As such, evaluation of cardiac performance may assist in adjusting the predetermined size of a CRD jacket.

          A CRD as described herein can be applied to the epicardium of a heart through a thoracotomy or through a minimally invasive procedure. For a minimally invasive procedure a CRD placement tool can be used to apply the CRD  
20 over the epicardium of the heart through a thoroscopic incision. According to this embodiment, a CRD placement tool includes a cannula, a stiff rod or wire and a guide tube. For placement of a CRD, the wire is threaded through the guide tube which is passed around the circumference of the base of the jacket. The CRD with wire and guide tube passed through the base opening are then passed into the  
25 cannula. The cannula is of sufficient length and diameter to enclose the CRD, wire and guide tube during passage of the placement tool through a thoroscopic incision. The placement tool is passed into the thoracic cavity and positioned at a point near the apex of the heart. When in position, the wire and guide tube are pushed out of the cannula away from the operator. Once outside the cannula, the wire and guide  
30 tube sufficiently expand the opening of the base of the CRD jacket to pass over the epicardial surface of the heart. When the CRD jacket is in position over the epicardial surface, the wire, guide tube and cannula can be removed. A second incision can then be made to provide access for suitable surgical instruments to secure or adjust the size of the CRD.

35           The invention will now be further described by reference to the drawings.

          FIG. 1 is a frontal view of one embodiment of a cardiac reinforcement patch 1. The CRD patch 1 shown here is a mesh biomedical material

2 having a thickened peripheral ring 3 which reinforces the peripheral edge 4 of the patch for attachment of the patch to the epicardial surface of the heart.

FIG. 2. is a perspective view of a CRD patch 10 in place on the epicardial surface of a heart 11, for example, over a cardiac aneurysm (not shown) of the heart. In one preferred embodiment, the patch 10 is sized to cover the extent of  
5 the cardiac aneurysm and is placed on the epicardial surface of the heart 11. In practice, the thorax is surgically opened and the region of the heart 11 with the aneurysm (not shown) is located and exposed. The patch 10 is placed over the aneurysm and sutured in place around the periphery 12 of the patch to provide  
10 sufficient constraint to prevent further dilation of the aneurysm.

FIG. 3 is a perspective view of one embodiment of a CRD jacket 15 according to the invention. According to the embodiment shown, the jacket 15 is a mesh material 16, and includes a circumferential attachment device 17 at the base end 18 of the CRD jacket. The apex end 24 of the jacket 15 is closed. The jacket 15  
15 shown also includes a slot 19 having opposing lateral edges 20 and 21, and fasteners (e.g. lateral attachment device 22 and 23) for selectively adjusting the volumetric size of the jacket 15. The CRD jacket 15 shown also includes radiopaque markers 25 for visualizing the surface of the heart through radiographic study.

FIG. 4 is an alternative embodiment of a CRD jacket 30. Similar to  
20 the embodiment shown in FIG. 3, the embodiment of FIG. 4 includes a base end 31 and an apex 32 end. The base end includes a circumferential attachment device 33 for securing the CRD jacket 30 to the heart. The CRD jacket 30 of FIG. 4 also includes a slot 34 having opposing lateral edges 35, 36. The lateral edges 35, 36 are shown pulled together at 37 by a lateral attachment device 38, for example, a suture.  
25 In contrast to the embodiment shown in FIG. 3, the embodiment shown in FIG. 4 has an opening 39 at the apex end 32 of the CRD jacket 30.

FIG. 5. is a perspective view of a CRD jacket 40 around a heart 41. According to the embodiment shown, at the base 42 of the jacket 40, there is a circumferential attachment device 43 which secures the CRD jacket 40 near the base  
30 of the heart 44. A slot 45, is shown with opposing lateral edges 46, 47 fastened together by a lateral attachment device 48. In the embodiment shown, the CRD jacket 40 has an opening 49 at the apical end 50 of the jacket. The apex of the heart 51 protrudes through the opening 49 at the apical end 50 of the jacket 40.

Still referring to FIG. 5, in a preferred embodiment, if one or more of  
35 the lateral attachment device 48 are made of an elastic material, such as silicone rubber, the device can provide a way of applying a graded constraint around the outside of the heart 41 to reduce cardiac dilation over time. In practice, the jacket would be placed over the heart 41 as shown, either over or under the parietal

pericardium (not shown). The circumferential attachment device 43 and lateral attachment device 48 would then be tightened to cause a constraining effect on the outside of the heart.

In a preferred embodiment, if one or more of the lateral attachment  
5 cords 48 is made of an elastic material, such as silicone rubber, surface pressure exerted on the epicardial surface of the heart varies as a function of the amount of dilation of the heart. This variable pressure has the effect of reducing the cardiac dilation to a certain point and then stopping because the surface pressure drops to a negligible amount. The amount of constraint or reduction in dilation that is  
10 accomplished over time and the resultant cardiac performance may be monitored radiographically using techniques known in the art, for example fluoroscopy, by observing radiographic markers (FIG. 4, 25), if present.

FIG. 6 is a schematic cross sectional view of an alternative  
embodiment of an arrangement for selectively adjusting the predetermined size of a  
15 jacket 53. According to this embodiment, an inflatable member 54 is inserted within the jacket 53 between the jacket 53 and the epicardial surface 55 of the heart 56. The inflatable member 54 includes a filling apparatus 57 for entry of a fluid (liquid or gas) to inflate the inflatable member 54 and reduce the predetermined size of the jacket 53.

FIG. 7 is a perspective view of a placement tool 60 which can be used  
20 for placement of a CRD jacket 61 around the epicardium of the heart. As shown here, the base end of the jacket 62 is held open by guide tube 63 through which is passed a wire or stiffening rod 64. The wire 64 can be removed from the guide tube 63 by pulling on the wire extraction grip 66. The placement tool 60 includes a  
25 cannula 65 which encloses the jacket 61, guide tube 63 and wire 64 during insertion of the tool into a thorascopic incision.

FIG. 8 is a perspective view of a placement tool 70 being employed  
to place a jacket 71 over the heart 72 on the outside of the parietal pericardium 73. The placement tool 70 is guided through a small incision in the thorax and the jacket  
30 71 is maneuvered into position over the heart 72. Once the jacket 71 is in proper position, the wire 74, which is passed through the guide tube 75 around the base 76 of the jacket 71, is extracted from the guide tube 75 by pulling on the wire extraction grip 77. The guide tube 75 is then extracted by pulling on the guide tube extraction grip 78. The cannula 79 is removed from the chest and the circumferential  
35 attachment cord (not shown in this view), and the lateral attachment cord 80 can be fastened to secure the jacket 71.

The above specification and drawings provide a description of a cardiac reinforcement device and method of using on the heart. Since many

embodiments of the invention can be made without departing from the spirit and scope of the invention, the invention resides in the claims hereinafter appended.

**WHAT IS CLAIMED IS:**

1. A cardiac reinforcement device, said device comprising:
  - a biomedical material which can be applied to the epicardial surface  
5 of the heart and which expands to a predetermined size,  
said predetermined size selected to constrain cardiac expansion beyond a  
predetermined limit.
- 10 2. The cardiac reinforcement device according to claim 1 wherein said  
biomedical material is an open mesh patch, said size selected for said patch  
to locally constrain cardiac expansion.
- 15 3. The cardiac reinforcement device according to claim 1 wherein said  
biomedical material is a jacket with said predetermined size selected for said  
jacket to surround the epicardial surface of the heart and circumferentially  
constrain cardiac expansion.
- 20 4. The cardiac reinforcement device according to claim 3 wherein said jacket  
has a base end, said base end having an opening for applying said jacket to  
the epicardial surface of the heart by passing the jacket over the epicardial  
surface of the heart such that when applied to said epicardial surface, said  
base end of said jacket is oriented toward the base of the heart.
- 25 5. The cardiac reinforcement device according to claim 3 wherein said jacket  
has an apex end such that when said jacket is applied to said epicardial  
surface, said apex end is oriented towards the apex of the heart.
- 30 6. The cardiac reinforcement device according to claim 5 wherein said apex end  
of said jacket has an opening for protrusion of the apex of the heart  
therethrough.
- 35 7. The cardiac reinforcement device according to claim 4 wherein said base end  
of said jacket further includes a securing arrangement for securing said jacket  
to said epicardial surface of the heart.
8. The cardiac reinforcement device of claim 7 wherein said securing  
arrangement for securing said jacket to said epicardial surface of the heart is

a circumferential attachment device which surrounds said opening at said base end of said jacket.

- 5 9. The cardiac reinforcement device according to claim 4 wherein said jacket includes a mechanism for selectively adjusting said predetermined size of said jacket surrounding the epicardial surface of the heart.
- 10 10. The cardiac reinforcement device according to claim 9 wherein said mechanism for selectively adjusting said predetermined size of said jacket is a slot, said slot having opposing lateral edges which decrease said predetermined size by moving said opposing lateral edges closer together.
- 15 11. The cardiac reinforcement device according to claim 10 including a lateral attachment device for fastening together said lateral opposing edges of said slot.
- 20 12. The cardiac reinforcement device according to claim 9 wherein said mechanism for selectively adjusting said predetermined size of said jacket is an inflatable member mounted between said jacket and the epicardial surface.
- 25 13. The cardiac reinforcement device according to claim 1 wherein said biomedical material is an open mesh material.
14. The cardiac reinforcement device according to claim 1 wherein said biomedical material is a polyester mesh.
15. The cardiac reinforcement device according to claim 1 wherein said biomedical material is silicon rubber.
- 30 16. The cardiac reinforcement device according to claim 1 wherein said biomedical material includes a radiopaque marker.
17. The cardiac reinforcement device according to claim 16 wherein said radiopaque marker is a platinum wire.
- 35 18. A cardiac reinforcement device, said device comprising:
  - a jacket of a biomedical material which can be applied to the epicardial surface of the heart and which expands to a predetermined

size, said predetermined size selected to surround the epicardial surface of the heart and circumferentially constrain cardiac expansion beyond a predetermined limit, said jacket comprising:

- 5 (i) a base end, said base end having an opening for applying said jacket to the epicardial surface of the heart by passing said jacket over the epicardial surface of the heart such that when applied to said epicardial surface, said base end of said jacket is oriented toward the base of the heart; and
- 10 (ii) a slot for selectively adjusting said predetermined size of said jacket, said slot having opposing lateral edges which decrease said predetermined size of said jacket by moving said opposing lateral edges together.

19. A cardiac reinforcement device, said device comprising:
- 15 - a jacket of a biomedical material which can be applied to the epicardial surface of the heart and which expands to a predetermined size, said predetermined size selected to surround the epicardial surface of the heart and circumferentially constrain cardiac expansion beyond a predetermined limit, said jacket comprising:
    - 20 (i) a base end, said base end having an opening for applying said jacket to the epicardial surface of the heart by passing said jacket over the epicardial surface of the heart such that when applied to said epicardial surface, said base end of said jacket is oriented toward the base of the heart; and
    - 25 (ii) an inflatable member mounted between said jacket and the epicardial surface of the heart for selectively adjusting said predetermined size of said jacket.

20. The cardiac reinforcement device according to claim 19 wherein said  
30 biomedical material is an open mesh material.

21. The cardiac reinforcement device according to claim 19 wherein said  
biomedical material is a polyester mesh.

- 35 22. A cardiac reinforcement device, said device comprising:
  - (a) a cone-shaped biomedical material having an apical end and a based end and which generally conforms to the external geometry of a patient's heart;

- (b) said cone-shaped biomedical material having a lateral slot providing for selective adjustment of a circumference of said cone-shaped biomedical material to a predetermined size;
- (c) said predetermined size selected to surround the surface of the heart and constrain cardiac expansion beyond a predetermined limit.
23. The cardiac reinforcement device according to claim 22 wherein said cone-shaped biomedical material is substantially non-elastic.
24. The cardiac reinforcement device according to claim 22 wherein said slot has opposing lateral edges which decreases said predetermined size of said circumference of said cone-shaped device by moving said opposing lateral edges together.
25. The cardiac reinforcement device according to claim 22 wherein said apical end of said device is open.
26. The cardiac reinforcement device according to claim 22 wherein said biomedical material is an open mesh material.
27. A cardiac reinforcement device for constraining cardiac size during diastole, said device comprising:
- (a) a biomedical material for contacting an epicardial surface of a patient's heart and configured to circumferentially surround said epicardial surface of said patient's heart;
- (b) said configured biomedical material having a base end and an apical end; and
- (c) said configured biomedical material providing cardiac constraint during diastole without substantially assisting cardiac contraction during systole.
28. The cardiac reinforcement device according to claim 27 wherein said biomedical material is substantially non-elastic.
29. The cardiac reinforcement device according to claim 27 wherein said configured biomedical material has a lateral slot for providing selective adjustment of a circumference of said biomedical material to a predetermined size.



30. The cardiac reinforcement device according to claim 29 wherein said slot has opposing lateral edges which decrease said predetermined size of said circumference of said biomedical material by moving said opposing lateral edges together.
- 5 31. The cardiac reinforcement device according to claim 27 wherein said apical end of said device is open.
32. A method for treating cardiac disease, said method comprising:
- 10 (a) selecting a cardiac reinforcement device, said cardiac reinforcement device comprising:
- (i) a biomedical material which can be applied to the epicardial surface of the heart and which expands to a predetermined size, said predetermined size selected to constrain cardiac expansion beyond a predetermined limit;
- 15 (b) applying said cardiac reinforcement device to the epicardial surface of the heart; and
- (c) securing said cardiac reinforcement device to said epicardial surface of the heart.
- 20 33. The method according to claim 32 wherein said cardiac reinforcement device is a jacket with said predetermined size selected for said jacket to surround the epicardial surface of the heart and circumferentially constrain cardiac expansion.
- 25 34. The method according to claim 32 wherein said cardiac reinforcement device is a patch, said size selected for said patch to locally constrain said cardiac expansion.
- 30 35. The method according to claim 32 wherein said cardiac reinforcement device is applied to the epicardial surface of the heart under the parietal layer of the pericardium.
36. The method according to claim 33 wherein said cardiac reinforcement device is applied to said epicardial surface via thorascopy.
- 35 37. The method according to claim 32 wherein said cardiac disease is heart failure.

38. The method according to claim 32 wherein said cardiac disease is cardiomyopathy.
39. The method according to claim 33 wherein said predetermined size of said jacket is reduced as cardiac size is reduced.
40. A method for reducing the diastolic volume of the heart, said method comprising:
- (a) selecting a cardiac reinforcement device, said cardiac reinforcement device comprising:
    - (i) a biomedical material which can be applied to the epicardial surface of the heart and which expands to a predetermined size, said predetermined size selected to constrain cardiac expansion beyond a predetermined limit;
  - (b) applying said cardiac reinforcement device to the epicardial surface of the heart; and
  - (c) securing said cardiac reinforcement device to said epicardial surface of the heart.
41. A method for treating valvular conditions of a patient's heart, said method comprising:
- (a) selecting a cardiac reinforcement device, said cardiac reinforcement device comprising:
    - (i) a biomedical material which can be applied to an epicardial surface of the heart and having a maximum predetermined size, said predetermined size selected to constrain cardiac expansion beyond a predetermined limit;
  - (b) applying said cardiac reinforcement device to said surface of the heart; and
  - (c) securing said cardiac reinforcement device to said surface of the heart.
42. The method for treating valvular conditions according to claim 41 wherein said valvular condition is valvular insufficiency.
43. The method for treating valvular conditions according to claim 41 wherein said biomedical material is a substantially non-elastic material.

44. A method for minimally invasive treatment of cardiac disease of a patient's heart, said method comprising:
- (a) passing a thoroscope into a first incision in said patient for intra thoracic visualization;
  - 5 (b) inserting a cardiac reinforcement device into a second incision in said patient's thorax, said cardiac reinforcement device comprising:
    - (i) a biomedical material which can be applied to an epicardial surface of the heart and having a maximum predetermined size, said predetermined size selected to surround the surface
    - 10 of the heart and circumferentially constrain cardiac expansion beyond a predetermined limit;
  - (c) applying said cardiac reinforcement device to said epicardial surface of said patient's heart;
  - (d) removing said thoroscope from said patient's thorax;
  - 15 (e) closing said first and said second incision in said patient's thorax.
45. The method according to claim 44 wherein said cardiac reinforcement device comprises:
- (a) a jacket having a base end and an apical end, said base end having an opening for applying said jacket to the surface of the heart by passing
  - 20 said jacket over said surface of the heart such that when applied to the surface, the base of the jacket is oriented toward the base of the heart.
46. The method according to claim 45 wherein said cardiac reinforcement device further comprises:
- (a) a cannula for passing said cardiac reinforcement device through said second incision;
  - (b) a guide tube, said guide tube capable of passing around a circumference of said base of said jacket;
  - 30 (c) a guide wire capable of passing through said guide tube.
47. The method according to claim 46 further comprising a step of:
- (a) passing said cannula into said second incision to a position for applying said jacket to said patient's heart;
  - 35 (b) passing through said cannula into said patient's thorax said jacket having said guide tube passed around said circumference of said base of said jacket and said guide wire passed through said guide tube;

- (c) applying said jacket over said surface of said heart such that said base of said jacket is oriented towards the base of said heart;
- (d) removing said guide wire from said guide tube;
- (e) removing said guide tube from said base of said jacket; and
- 5 (f) removing said cannula from said patient.

FIG. 1

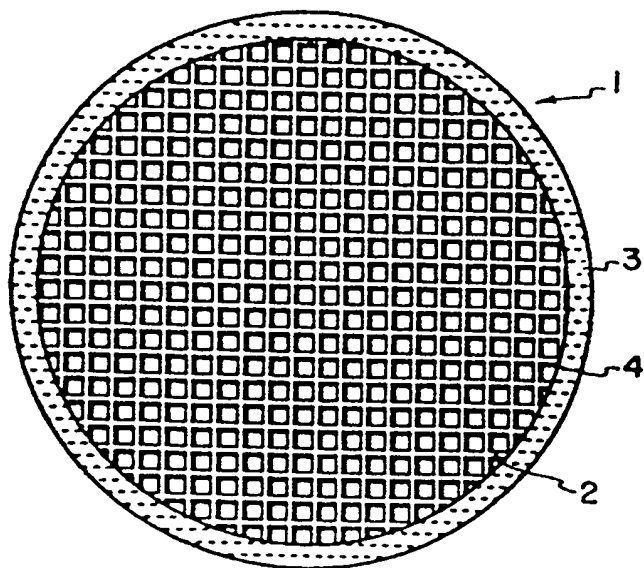


FIG. 2

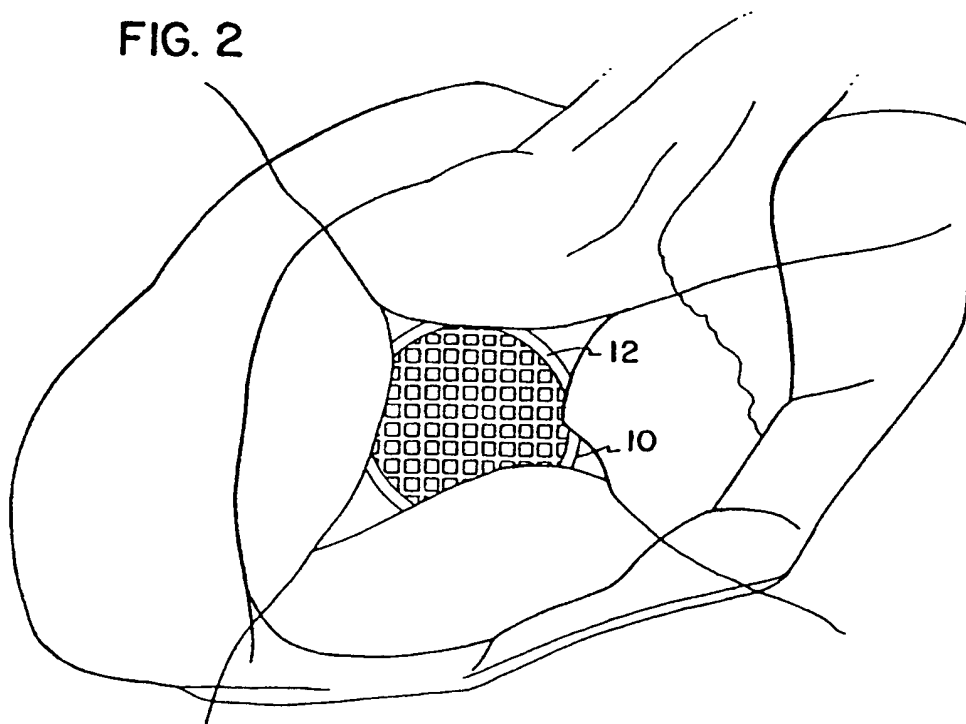


FIG. 3

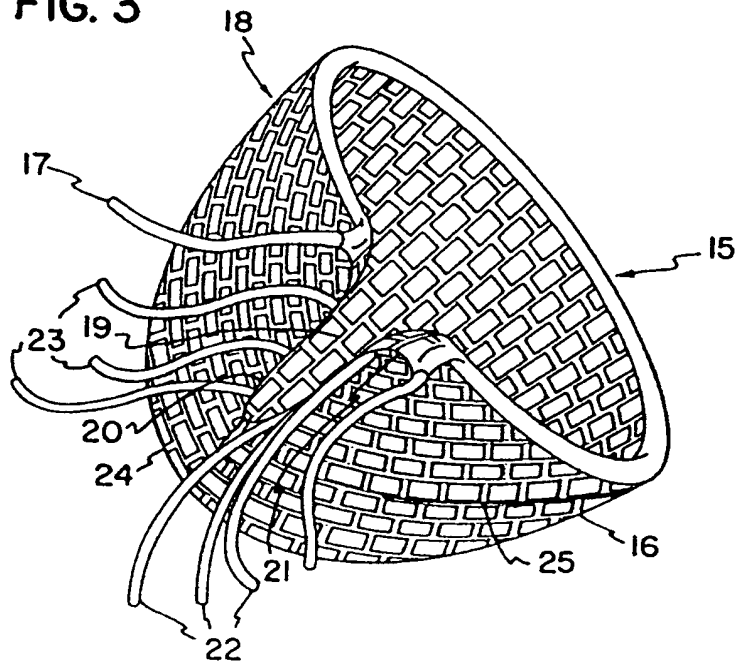


FIG. 4

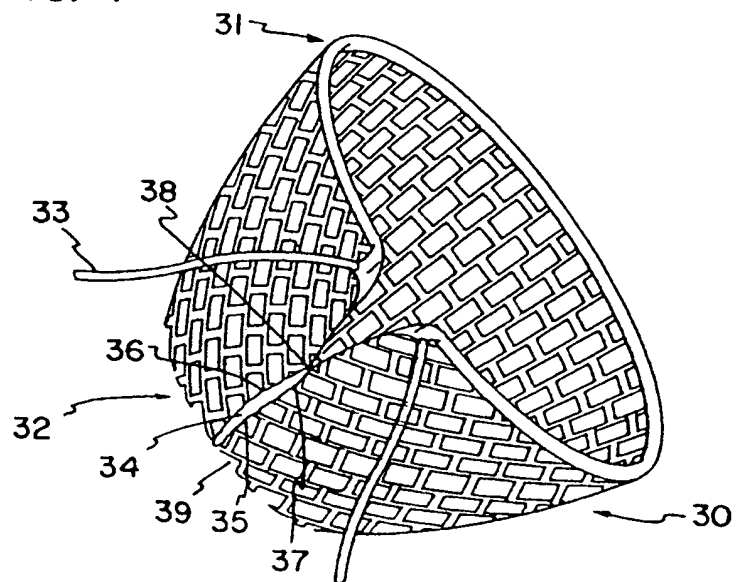


FIG. 5

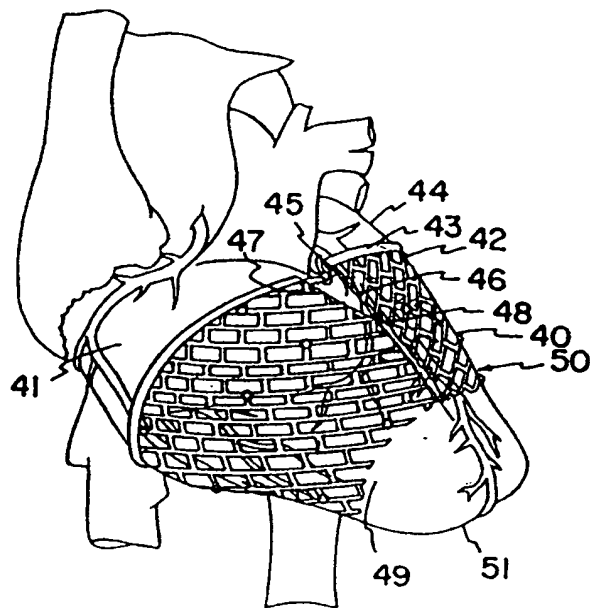
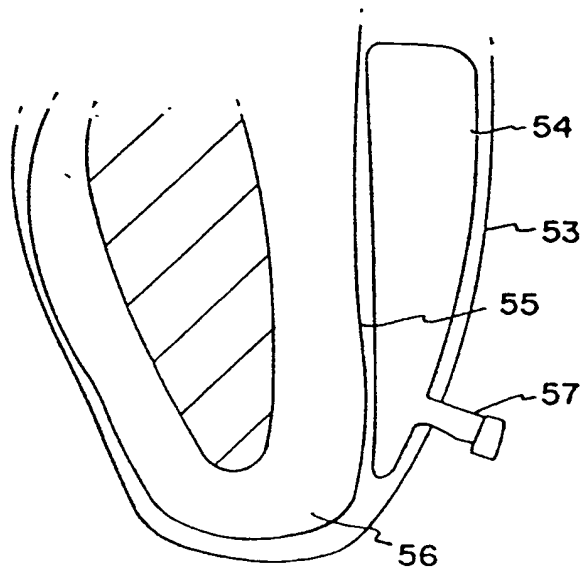


FIG. 6



4/4

FIG. 7

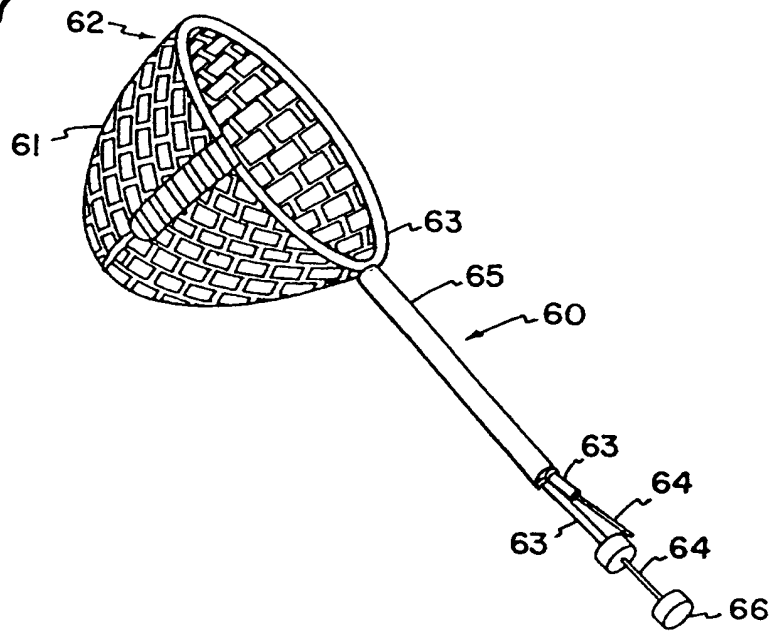
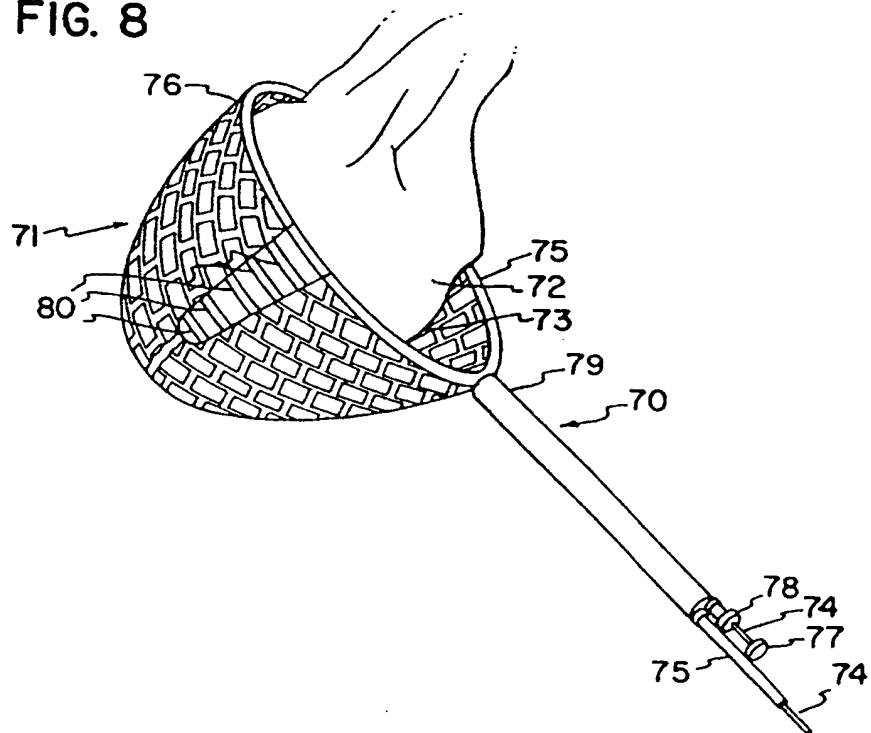


FIG. 8





## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 97/17898

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 6 A61F2/02

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,A	US 5 603 337 A (JARVIK) 18 February 1997 see abstract; figure 2 ---	1,18,19, 22,27
A	US 4 403 604 A (WILKINSON) 13 September 1983 see abstract; figures 1,2 ---	1,18,19, 22,27
A	US 5 507 779 A (ALTMAN) 16 April 1996 see abstract; figure 4 -----	1,18,19, 22,27



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

## \* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

17 February 1998

Date of mailing of the international search report

23.02.98

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Papone, F

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US 97/17898

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 32-47  
because they relate to subject matter not required to be searched by this Authority, namely:  
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest
- ☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 97/17898

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5603337 A	18-02-97	NONE	
US 4403604 A	13-09-83	NONE	
US 5507779 A	16-04-96	NONE	